Remarks/Arguments

A. Summary of the Claims

Claims 1 and 18 are amended to recite "a patient undergoing general anesthesia." Support for this language can be found in the specification and claims as originally filed. *See*, *e.g.*, specification at page 13, lines 1-11 (*e.g.*, Example 1—patient in the double blind study underwent a general anesthesia). Claim 18 is further amended to recite "preventing or reducing," and non-limiting support can be found in the specification at page 4, lines 23-25. Claim 16 is amended to delete the term "immediately," and support can be found in the specification and claims as originally filed. *See*, *e.g.*, original claim 4.

Claim 24 is added new. Support for this claim can be found, for example, in original claim 7 or at page 4, lines 3-4 of the specification.

Claims 1-24 are pending in this case.

B. The Obviousness Rejections Are Overcome

1. Claims 1-7, 10-19, 21-22, and 23 are not rendered obvious over U.S. Patent 6,340,695 to Gervais

a. Summary of the rejection

Claims 1-7, 10-19, 21-22 and 23 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 6,340,695 to Gervais. It is alleged that this reference discloses "...a rapid onset formulation comprising pyridoxine HCl and doxylamine succinate useful in the treatment of nausea and vomiting comprising administration of a therapeutically effective amount of the composition." Action at page 2 (internal citations omitted). Gervais is also alleged to teach "the formulation of Doxylamine succinate and pyridoxine hydrochloride are used in the human and veterinary fields of medicine whenever symptoms of nausea and/or vomiting require medical intervention. *Id.* at page 3 (internal citations omitted and underline in original). From this, the

Action concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Doxylamine succinate and pyridoxine HCl formulation to reduce post-surgical vomiting because the reference teaches the treatment of vomiting and nausea in general." *Id.*

b. Summary of the arguments

Applicant disagrees. The claims, prior to any amendment made above, were not rendered obvious by the cited references. However, in an effort to further the prosecution and secure prompt allowance, independent claims 1 and 18 are now directed to "a patient undergoing general anesthesia." At least this element is not disclosed or suggested in the cited Gervais reference.

For instance, and as discussed in detail in the following sections, Applicant respectfully submits that a method of reducing post-surgical vomiting comprising administering to a patient undergoing general anesthesia a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride, as recited in claims 1 and 18, would not have been obvious on the priority date of Applicant's invention to a person of ordinary skill in the art. Further, Applicant's invention has surprising and unexpected results and also satisfies a long-felt need in the art which was not solved by others.

c. A prima facie case of obviousness is not present

In order to maintain the present obviousness rejection, there must be a showing that Gervais discloses or suggests reducing post-surgical vomiting in "a patient undergoing general anesthesia." MPEP § 2142 (explaining the requirements for establishing a *prima facie* case of obviousness). In essence, the question is whether differences between the prior art and Applicant's invention, namely, the method comprising administering a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride to a patient undergoing general

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anesthesia—and its effects on reducing post-surgical vomiting in the patient—are such that applicant's invention as a whole would have been obvious. See In re Wright, 848 F.2d 1216 (Fed. Cir. 1988) ("[I]t is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties, and the problem it solves." The cited Gervais reference fails in this respect.

For instance, Gervais generally teaches a rapid onset formulation comprising Doxylamine Succinate and Pyridoxine Hydrochloride as active ingredients. Specific *in-vitro* dissolution profiles for the formulation are also disclosed. The formulation is said to be useful in treating nausea and vomiting.

However, Applicant submits that in the present case, neither the claimed method itself—administering to a patient undergoing general anesthesia a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride; the result of the method—reducing post-surgical vomiting; or the problem Applicant solves—controlling post-operative vomiting and alleviating post-operative patient discomfort (as stated for example on page 2, lines 8-24 of the specification as filed)—were taught or suggested in Gervais. Thus the invention as a whole has clearly not been rendered obvious by the cited prior art. Stated another way, Applicant submits that a *prima facie* case of obviousness has not been established for at least three reasons.

First, a person of skill in the art would not find, in Gervais, or in the knowledge generally available to him or her, any suggestion or motivation to specifically use a combination of Doxylamine Succinate and Pyridoxine Hydrochloride in a patient undergoing general anesthesia for reducing post-surgical vomiting. As acknowledged by the Examiner, Gervais does not teach "reducing post-surgical vomiting" or "treating post-surgical vomiting". Action page 2. Gervais does not even mention surgical conditions or anesthesia. Thus, no incentive in Gervais appears

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to be present that would lead a person skilled in the art to modify the teachings by Gervais towards the claimed method. See MPEP § 2143.01 ("The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.") (underlines in original). Further, Applicant respectfully notes that "obvious to try" is not the appropriate standard under 35 U.S.C. § 103. The Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720 (Fed. Cir. 1990) (noting that 'obvious to try' is not to be equated with obviousness under 35 U.S.C. 103.).

Second, Applicant submits that the experimental results on the effectiveness of the combination of the two known products for the reduction, prophylaxis and treatment of post-surgical vomiting were quite unexpected. The results summarized in Table 1, page 14, of Applicant's specification clearly show that the beneficial effects of the combination reduce post-surgical <u>vomiting</u>, which allows patients to benefit from a rapid recovery (1.5 days, compared to 4 with the placebo). Very surprisingly, it appears that the combination has little or no effect on patient <u>nausea</u> in post-surgical situations. Such surprising results support the fact that there is a lack of a reasonable expectation of success in the cited reference or from a person of skill in the art that modifying Gervais to encompass Applicant's invention would work. *See* MPEP § 2143.02. In addition, unexpected results as such, and as commensurate with invention as claimed in amended claims 1 and 18, are further evidence of nonobviousness, as they constitute secondary considerations of nonobviousness. *See* MPEP § 716.02(a)-(c).

Third, Gervais does not teach or suggest every limitation of independent claims 1 or 18, as amended. Again, it fails to disclose "administering to a patient undergoing general anesthesia a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride."

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Therefore, Applicant respectfully submits that all three basic criteria for establishing a prima facie case of obviousness are missing (see MPEP § 2142), and the present obviousness rejection is overcome.

d. Secondary considerations of non-obviousness are present

As explained above, Applicant has shown the existence of surprising and unexpected results which is evidence of nonobviousness. § MPEP 716.02(a)[III]. In addition, Applicant submits that the claimed method satisfies a long felt need which was recognized, persistent, and not solved by others. MPEP § 716.04. The need for reducing, preventing and treating postsurgical vomiting has been persistently recognized since 1970 at the latest, as shown in the enclosed PubMed list of 47 review articles (attached as Appendix A) linked with anesthesia and surgery, published between 1968 and 2006. These review articles were designated by PubMed as "related articles" to an article by Marley entitled "Postoperative nausea and vomiting: the outpatient enigma" (June 1996), no. 26, on the list attached at Appendix A, as sorted out by the publication dates. Furthermore, it is known that current anti-emetics used to prevent or reduce vomiting after surgery are either poorly efficient or cause undesirable side effects such as dystonic reactions and somnolence. Applicant's specification at page 2. Moreover, in June 2003, i.e., just before the filing date of the present application, an article by McGrath et al. entitled "postoperative recovery and discharge", the abstract of which is attached as Appendix B. states that PONV (postoperative nausea and vomiting) are still common. Thus, the long-felt need for reducing, preventing and treating post-surgical vomiting had not been satisfied by others before Applicant's invention. Control of post-operative vomiting then remained an essential problem to solve, for patient and clinician. See In re Dow Chemical Co., 837 F.2d 469 (Fed. Cir. 1988) ("Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness."); see also In re Mahurkar Patent Litigation, 831 F. Supp.

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1354 (N.D. Ill. 1993), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995) ("The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.").

Further, as noted in the above paragraph, vomiting is a known side effect of general anesthesia in surgical situations. Vomiting rarely occurs when a local anaesthetic is involved. The anti-emetic and anti-nauseant properties of the combination of Doxylamine Succinate and Pyridoxine Hydrochloride have been known since the 1950's to treat hyperemesis gravidarum in pregnant women. See Brent (1983), a copy of which was submitted to the Patent Office in Applicant's Information Disclosure Statement as "C1" on December 1, 2003; see also Applicant's specification at page 3 lines 1-3. Despite these facts, there has been no suggestion to use a combination of Doxylamine Succinate and Pyridoxide Hydrochloride for the reduction, prophylaxis and treatment of post-surgical vomiting prior to Applicant's invention (more than thirty years later). MPEP § 716.04[I] (explaining that "the long-felt need must not have been satisfied by another before the invention by applicant.").

Further, Example 1 of Applicant's specification clearly demonstrates that Applicant's invention indeed satisfies the long felt need with regard to reduction, prophylaxis, and treatment of post surgical vomiting. This fact also clearly pleads in favor of the non-obviousness of the present invention. MPEP § 716.04[I] (explaining that "the invention must in fact satisfy the long-felt need").

e. Summary of conclusions

In summary, claims 1 and 18 are direct to the use of the combination, for the reduction, as well as prophylaxis and treatment, of vomiting, in a patient undergoing surgical intervention with general anaesthesia. The cited Gervais reference fails to teach or suggest at least this aspect of Applicant's claimed invention. Further, Applicant has shown that the claimed invention (1) provides surprising and unexpected results and (2) satisfies a long-felt need which was recognized, persistent, and not solved by other. For at least these reasons, the present claims are not rendered obvious over Gervais.

Therefore, Applicant respectfully requests that the rejection of claims 1-7, 10-19, 21-22 and 23 under 35 U.S.C. § 103(a) as being obvious over Gervais be withdrawn.

2. Dependent claims 8, 9, and 20 are not rendered obvious over Gervais in view of Ansel et al.

Dependent claims 8, 9, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gervais in view of Ansel et al.

Applicant disagrees. This rejection of these dependent claims is based on the primary reference of Gervais. Because independent claims 1 and 18 are not obvious over Gervais (as discussed above), claims depending from these independent claims are also not obvious for the same reasons discussed above. Thus, the arguments presented above are incorporated by reference. *See* MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious."). Therefore, the remaining obviousness rejections are overcome and should be withdrawn.

Applicant further notes that Ansel *et al.* merely discloses that delayed-release products usually are enteric coated tablets. Therefore, Applicant submits that should a person of skill in the art combine the teachings by Gervais with those by Ansel *et al.*, he/she would certainly not

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be led to the present invention as claimed, particularly since neither one of these references or their combination teach or suggest a method of reducing post-surgical vomiting comprising administering to a patient undergoing general anesthesia a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride.

In view of the above, Applicant requests that the present obviousness rejection of claims 8, 9 and 20 be withdrawn.

C. The Obviousness-Type Double Patenting Rejection Is Overcome

Claims 1-6, 13-18, and 19 are rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 25-29 and 30 of U.S. Patent Application No. 09/885,051. Applicant notes that Application No. 09/885,051 issued into U.S. Patent No. 6,340,695 to Gervais which is the same reference used to support the above discussed obviousness rejections under 35 U.S.C. § 103(a).

Applicant disagrees with the obviousness-type double patenting rejection. Because this rejection is based on the same reference used to support the § 103(a) rejections, the arguments made above equally apply to this rejection and are therefore incorporated by reference. Applicant requests that this rejection be withdrawn.

D. Conclusion

Applicant believes that this is a complete response to the Office Action mailed June 15, 2006. The present claims are in a condition for allowance, and such favorable action is requested.

A petition for a two-month extension of time is being submitted concurrently with this document. The Commissioner is authorized to deduct the two-month extension of time fee of \$225.00 for small entity status applications and any additional fees under 37 C.F.R. §§ 1.16 to 1.21 required for any reason relating to the enclosed materials from Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:032US.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3030 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Michael R. Krawzsenek

Reg. No. 51,898

Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, Texas 78701 (512) 536-3020 (512) 536-4598 (facsimile)

Date:

November 15, 2006

APPENDIX A
(PubMed List of 47 Review Articles)

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New/Noteworthy 50 E-Utilities		-	Prevention, recognition, and management of nursing complications in the intraoperative and postoperative surgical patient.					
PubMed Services Journals Database		Nurs Clin Nort PMID: 166983	h Am. 2006 .	Jun;41(2):151-	71, v. Reviev			
MeSH Database	□2:	Smith I.					F	Related Articles, Links
Single Citation Matcher Batch Citation Matcher Clinical Queries Special Queries		Dissecting th J Perioper Prace PMID: 167246	t. 2006 May;	16(5):244-8. R	Review.	esthetist's	view.	
LinkOut My NCBI	□3:	Foubert J, Vaes	ssen G.				F	Related Articles, Links
Related Resources Order Documents NLM Mobile		Nausea: the Eur J Oncol Nu PMID: 157743	ırs. 2005 Maı	;9(1):21 - 32. R				
NLM Catalog NLM Gateway	□4:	Eberhart LH, G	eldner G, Ho	rle S, Wulf H.			F	Related Articles, Links
TOXNET Consumer Health Clinical Alerts ClinicalTrials.gov PubMed Central		[Prophylaxis surgery] Ophthalmologe PMID: 149994	. 2004 Sep;1	01(9):925-30. 1	Review. Gen	_	r outpati	ent ophthalmic
	□ 5:	Callesen T.					F	Related Articles, Links
		Inguinal herr Dan Med Bull. PMID: 136772	2003 Aug;50	0(3):203-18. Re	eview.	convalesce	ence.	
	□ 6:	McGrath B, Ch	ung F.				F	Related Articles, Links
		Postoperativ Anesthesiol Cli PMID: 128124	n North Ame	erica. 2003 Jun	;21(2):367-8	6. Review.		
	□7:	Cameron D, Ga	m TJ.				F	Related Articles, Links
		Management Anesthesiol Cli PMID: 128124	n North Ame	erica. 2003 Jun	;21(2):347-6	_	mbulato	ry surgery.
	□8:	Bryant R.					F	telated Articles, Links

	Managing side effects of childhood cancer treatment. J Pediatr Nurs. 2003 Apr;18(2):113-25. Review. PMID: 12720208 [PubMed - indexed for MEDLINE]	
□9:	Marley RA, Swanson J.	Related Articles, Links
	Patient care after discharge from the ambulatory surgical cer J Perianesth Nurs. 2001 Dec;16(6):399-417; quiz 417-9. Review. PMID: 11740781 [PubMed - indexed for MEDLINE]	nter.
□10:	Arif AS, Kaye AD, Frost E.	Related Articles, Links
	Postoperative nausea and vomitinga review. Middle East J Anesthesiol. 2001 Jun;16(2):127-54. Review. PMID: 11565430 [PubMed - indexed for MEDLINE]	
□11:	Fuchs-Buder T, Mencke T.	Related Articles, Links
	Use of reversal agents in day care procedures (with special postoperative nausea and vomiting). Eur J Anaesthesiol Suppl. 2001;23:53-9. Review. PMID: 11766248 [PubMed - indexed for MEDLINE]	reference to
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	Outpatient general anaesthesia for oral surgery. Singapore Dent J. 2000 Dec;23(1 Suppl):29-37. Review. PMID: 11699360 [PubMed - indexed for MEDLINE]	
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	Prevention and treatment of postoperative nausea and vomit Drugs. 2000 Feb;59(2):213-43. Review. PMID: 10730546 [PubMed - indexed for MEDLINE]	ing.
□ 14:	Mann E.	Related Articles, Links
	Using acupuncture and acupressure to treat postoperative energy Prof Nurse. 1999 Jul;14(10):691-4. Review. PMID: 10481718 [PubMed - indexed for MEDLINE]	mesis.
□ 15:	Capili B, Anastasi JK.	Related Articles, Links
	A symptom review: nausea and vomiting in HIV. J Assoc Nurses AIDS Care. 1998 Nov-Dec;9(6):47-56. Review. PMID: 9805296 [PubMed - indexed for MEDLINE]	
□16:	Williams AR, Conroy JM.	Related Articles, Links
	The anesthetic management of the pediatric strabismus patie J AAPOS. 1998 Apr;2(2):113-5. Review. PMID: 10530973 [PubMed - indexed for MEDLINE]	ent.
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	A continuing postoperative complication: nausea and vomiting why, and what are the contributing factors? A review. CRNA. 1998 Feb;9(1):19-29. Review. PMID: 9624943 [PubMed - indexed for MEDLINE]	ngwho is affected,
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□22:	Haynes GR, Bailey MK.	Related Articles, Links
	Postoperative nausea and vomiting: review and clinical approach Med J. 1996 Oct;89(10):940-9. Review. PMID: 8865784 [PubMed - indexed for MEDLINE]	roaches.
□23:	Tate S, Cook H.	Related Articles, Links
	Postoperative nausea and vomiting. 2: Management and treater Br J Nurs. 1996 Sep 26-Oct 9;5(17):1032-9. Review. PMID: 8918762 [PubMed - indexed for MEDLINE]	atment.
□24:	Tate S, Cook H.	Related Articles, Links
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□ 25:	Kaufman S, Martin-Sheridan D.	Related Articles, Links
	Postoperative nausea and vomiting after strabismus surgery: treatment, and implications for practice. CRNA. 1996 Aug;7(3):139-43. Review. PMID: 8850992 [PubMed - indexed for MEDLINE]	mechanisms,
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□ 27:	Spires R.	Related Articles, Links
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□ 28:	Marley RA, Moline BM.	Related Articles, Links
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□ 29:	Goebel C.	Related Articles, Links
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□32:	Kenny GN.	Related Articles, Links
	Risk factors for postoperative nausea and vomiting. Anaesthesia. 1994 Jan;49 Suppl:6-10. Review. PMID: 8129161 [PubMed - indexed for MEDLINE]	
□33:	Hirsch J.	Related Articles, Links
	Impact of postoperative nausea and vomiting in the surgical sanaesthesia. 1994 Jan;49 Suppl:30-3. Review. PMID: 8129160 [PubMed - indexed for MEDLINE]	setting.
□34:	White PF, Smith I.	Related Articles, Links
	Impact of newer drugs and techniques on the quality of amb J Clin Anesth. 1993 Nov-Dec;5(6 Suppl 1):3S-13S. Review. PMID: 8292366 [PubMed - indexed for MEDLINE]	ulatory anesthesia.
□35:	Parnass SM.	Related Articles, Links
	Ambulatory surgical patient priorities. Nurs Clin North Am. 1993 Sep;28(3):531-45. Review. PMID: 8367324 [PubMed - indexed for MEDLINE]	
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	[Prevention of nausea and vomiting in ambulatory anesthesia Cah Anesthesiol. 1993;41(4):393-402. Review. French. No abstract availa PMID: 8402288 [PubMed - indexed for MEDLINE]	-
□37:	Dandoy M.	Related Articles, Links
	[Characteristic problems posed to the anesthetist by ambulate ophthalmology] Cah Anesthesiol. 1993;41(4):361-5. Review. French. PMID: 8402283 [PubMed - indexed for MEDLINE]	ory surgery in
□38:	Rabey PG, Smith G.	Related Articles, Links

	Anaesthetic factors contributing to postoperative nausea and Br J Anaesth. 1992;69(7 Suppl 1):40S-45S. Review. No abstract available PMID: 1486013 [PubMed - indexed for MEDLINE]	•
□39:	Lerman J.	Related Articles, Links
	Surgical and patient factors involved in postoperative nausea Br J Anaesth. 1992;69(7 Suppl 1):24S-32S. Review. No abstract available PMID: 1486011 [PubMed - indexed for MEDLINE]	
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<u> </u>	vomiting? Am J Gastroenterol. 1988 Aug;83(8):803-5. Review. No abstract availabl PMID: 3293430 [PubMed - indexed for MEDLINE]	e.
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□ 46:	McKie BD.	Related Articles, Links
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	effects. Aust N Z J Surg. 1970 Feb;39(3):311-4. Review. No abstract available. PMID: 4910465 [PubMed - indexed for MEDLINE]	
□ 47:	Burnap TK, Vaugh RW.	Related Articles, Links
	Complications of the postoperative period. Clin Anesth. 1968;3:372-9. Review. No abstract available. PMID: 4902369 [PubMed - indexed for MEDLINE]	
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APPENDIX B (McGrath *et al.* Abstract)



1: Anesthesiol Clin North America. 2003 Jun;21(2):367-86.

Postoperative recovery and discharge.

McGrath B, Chung F.

Department of Anesthesia, Toronto Western Hospital, University Health Network, University of Toronto, 399 Bathurst Street, EC 2-046 Toronto, Ontario, Canada M5T 2S8.

Ambulatory surgery provides quality care that is cost-effective. The use of innovative surgical and anesthetic techniques will allow larger numbers of patients to take advantage of the benefits of undergoing an elective operation on an ambulatory basis. Anesthesiologists will be faced with more complex surgery, which will require careful selection and assessment of patients to ensure continuity of the excellent safety record of ambulatory anesthesia. Minor adverse events, such as pain and PONV, are still common. The occurrence of these minor adverse advents is now the major area of quality assessment and an area where improvement could be targeted. Fast tracking facilitates earlier discharge, but we must ensure this has benefit to the patient as speedy discharge may mask the true incidence of adverse minor symptoms. This can lead to patient dissatisfaction and a poor impression of ambulatory surgery.

PMID: 12812401 [PubMed - indexed for MEDLINE]

Related Links

Anaesthetic strategies towards developments in day care surgery. [Eur J Anaesthesiol Suppl. 2001] PMID: 11766244

Inquinal hernia repair: anaesthesia, pain and convalescence.

[Dan Med Bull. 2003] PMID: 13677240

A comparison of infraclavicular nerve block versus general anesthesia for hand and wrist day-case surgeries.

[Anesthesiology. 2004] PMID: 15220781 Fast-tracking after ambulatory surgery. [J Perianesth Nurs. 2001] PMID: 11740779

Ambulatory anesthesia: past, present, and future. [Int Anesthesiol Clin. 1994] PMID: 7960169